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21

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,398	11/13/2001	Holger Bengs	114750.2600	4117

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EXAMINER

PRATS, FRANCISCO CHANDLER

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/869,398

Applicant(s)

BENGST ET AL.

Examiner

Francisco C Prats

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on June 4, 2004, and July 21, 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendments filed June 4, 2004, and July 21, 2004, have been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claims 21-41 are pending and are examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21-41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Specifically, the limitations requiring 0% branching and "the degree of crystallinity of the resistant starch is greater than 65%" lack support in the disclosure as filed. The asserted

Art Unit: 1651

support for the 0% branching limitation lies in statements that the branching was below the level of detection. However, this is not the same as 0%. The two values are sufficiently different such that a new matter holding is required.

With respect to a requirement of a degree of crystallinity of "greater than 65%", the specification as filed contains no such limitation. Thus, the specification fails to provide literal support for the cutoff point as being 65%. Even if the single retrogradation example inherently results in 65% crystallinity, or greater, it is not clear where applicant derives the apparently arbitrarily selected lower limit now recited in the claims. Moreover, given the single retrogradation example, it is not clear that the specification as filed provides sufficient representative examples of the full scope of the claims as amended, which encompass values ranging from greater than 65% to 100%. In sum, because the specification as filed fails to provide clear support for the new claim language, a new matter rejection is clearly proper.

Claim Rejections - 35 USC § 103

Claims 21-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kossman et al (WO 95/31553) in view of Henley

Art Unit: 1651

et al (U.S. Pat. 5,409,542) and Zallie et al (U.S. Pat. 5,480,669), and in further view of Brown (WO 96/08261).

Kossman describes the production of a linear α -1,4 glucan from sucrose, using amylosucrase, and the use of the glucan in foods and pharmaceuticals. Kossman discloses that the glucan does not contain any branch points. See page 8, last sentence ("[a]ccording to the invention it could be shown that the product of the reaction catalyzed by amylosucrase are linear α -1,4 glucans **that are not branched as has been assumed so far** (see above).") See also page 36, last sentence of the first paragraph ("[w]ith the available analytical methods it was not possible to detect branching in the synthesis products.") Thus, Kossman describes the linear α -1,4 glucan product recited in applicant's claims, clearly meeting the limitation requiring 0% branch points.

Kossman differs from the claims in that Kossman does not explicitly disclose the use of the glucan in the production of resistant starch. However, each of Henley/Zallie discloses that linear α -1,4 glucans such as amylose are suitable for the production of resistant starch. See Henley at column 2, lines 2-4. ("This starch product when added to foods will contribute to the total dietary fiber present in the foods.") The molecular weight of the Henley's resistant starches includes

Art Unit: 1651

values ranging from 17 kD to 156 kD, well within the ranges recited in claims 27-29. Note that although the unbranched amylose products are not prepared using amylosucrase, they are virtually indistinguishable therefrom, since the amylosucrase-polymerized products have an essentially identical chemical structure to the enzymatically debranched products.

See also Zallie, at paragraph spanning columns 1 and 2; also at Examples I through III, at columns 4-7, describing the use of linear α -1,4 glucans prepared by debranching as a fiber source when combined with extruded foods including pasta. Note that flours and pasta inherently contain vitamins, as recited in claim 21. Moreover, because the mixing of the resistant starch and other ingredients will inherently result in "enrobing" of some of the compounds present, Zallie is properly considered to meet this limitation as well. Also, as discussed above, although the unbranched amylose products are not prepared using amylosucrase, they are virtually indistinguishable therefrom, since the amylosucrase-polymerized products have an essentially identical chemical structure to the enzymatically debranched products.

Thus, because the linear glucans of Kossman are essentially identical to the glucans used by Henley/Zallie to produce resistant starches, the artisan of ordinary skill viewing

Art Unit: 1651

Kossman in light of Henley/Zallie clearly would have been motivated to have produced resistant starch from the linear amylosucrase-polymerized glucans disclosed in Kossman. Moreover, in view of the fact that Brown directly discloses the suitability of resistant starches as carriers for bifidobacteria, such a use clearly must be considered obvious.

Further still, because the asserted combination of references teaches the suitability of using linear glucans produced in the same manner as claimed, in the same applications as claimed (resistant starch), one of ordinary skill would have reasonably expected the resulting product to have had the crystallinity properties recited in the claims as amended. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). In sum, because the prior art suggests the desirability of practicing the subject matter in the claims as amended, a holding of obviousness is clearly required.

All of applicant's argument filed June 4, 2004, and July 21, 2004, has been fully considered but is not persuasive of

Art Unit: 1651

error. With respect to the inherent presence of phosphorus in starch, argued by applicant, note that the Galliard reference referred to by applicant in support of this assertion is not present in the application filewrapper. However, official notice is taken of the fact that starch generally contains small amounts (less than 1%) of phosphorus, generally accepted to be in the form of phosphoric acid esters. Thus, the rejections over prior art references describing debranched starch are properly withdrawn.

However, the process in Kossman does not result in glucan molecules having phosphorus attached thereto, and necessarily produces glucans having the claimed degree of branching, since Kossman's process uses the same enzyme and starting materials as applicant. Kossman therefore remains applicable to the claims as amended. Moreover, because the artisan of ordinary skill viewing the Henley, Zallie and Brown references clearly would have considered the formation of resistant starch prepared from Kossman's linear glucans obvious, the obviousness rejection must be maintained. While it is noted that Kossman does not explicitly teach the production of resistant starch, it is respectfully pointed out that Kossman is applied in combination with additional references teaching the desirable applications of resistant starch. Thus, in response to applicant's arguments

Art Unit: 1651

against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In sum, as stated above, because the asserted combination of references teaches the suitability of using linear glucans produced in the same manner as claimed, in the same application as claimed (resistant starch), one of ordinary skill would have reasonably expected the resulting product to have had the properties recited in the claims as amended. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). Because the prior art suggests the desirability of practicing the subject matter in the claims as amended, the holding of obviousness is properly maintained.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS**

Art Unit: 1651

ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

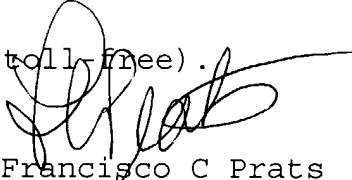
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C Prats whose telephone number is 571-272-0921. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can be reached on 571-272-0926. The fax phone number for the

Art Unit: 1651

organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Francisco C Prats
Primary Examiner
Art Unit 1651

FCP